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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,375	01/30/2002	J. Gregor Sutcliffe	22908-0002 C1	3744

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EXAMINER	
HAYES, ROBERT CLINTON	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 08/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/062,375	SUTCLIFFE ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/30/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. An application in which the benefits of an earlier application are desired must contain a specific reference to all prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. In addition, the status of each application (e.g, patent no. or now abandoned) must also be made in the first sentence.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the mailing address (P.O. Box) of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,479,642 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the human cortistatin of SEQ ID NO: 26, and the recited fragments thereof, in '642 are identical to that recited in the instant application. However, pharmaceutical compositions of these cortistatin polypeptides are claimed within the instant application, and not in '642.

It would have been obvious to one of ordinary skill within the art at the time of filing the instant application to make pharmaceutical compositions of biologically useful peptide hormones, such a cortistatin, because such is routine within the art, and because columns 3-4, 34, 37-38 & 53-54 of '642 describe pharmaceutical compositions of cortistatin, which includes the recited dosages (e.g., col. 34 (lines 48-54, where 0.1 *u*M in 5L of plasma in a human= 500 mg)) (e.g., col. 53, where dosages of 0.1 *u*g to 10 *u*g are

described for the rat, which is approximately 500X smaller than a human; thereby, making human dosages of about 50 *u*g to about 5 mg (w/w) also obvious for administration).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pharmaceutical compositions comprising the specific isolated and purified cortistatin polypeptides of SEQ ID NO: 26, or structurally and functionally defined fragments thereof, does not reasonably provide enablement for any biological functional equivalent proteins with no defined structural characteristics. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The name "human cortistatin" (as it relates to how it is defined on pages 4, 17, 23 & 28 of the specification) does not sufficiently characterize and enable the pharmaceutical composition comprising the polypeptides that are encompassed by the claims, because the inclusion of any "analog", "allelic variants", "substitutions, insertions, and deletions" with "like functional properties" (i.e., biologically functional equivalent proteins) within the definition of a cortistatin polypeptide sets forth no

structural characteristics. In particular, the specification does not teach which particular amino acids are critical for any cortistatin polypeptide's function, nor how to distinguish such from any different polypeptide sequence that possesses none of the desired functions of the instant invention. For example, Rudinger states on page 3 that "it is impossible to attach a unique significance to any residue in a sequence. A given amino acid will not by any means have the same significance in different peptide sequences, or even in different positions of the same sequence." Rudinger further states on page 6 that "the significance of particular amino acid sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study." Therefore, the lack of guidance provided in the specification as to what minimal structural requirements are necessary for any "human cortistatin" protein's function would prevent the skilled artisan from determining whether any mutation to a cortistatin polypeptide could be made that retains the desired function of the instant invention, because any random mutation manifested within such a protein would be predicted to adversely alter its biologically active 3-dimensional conformation, without requiring undue experimentation to determine otherwise.

5. Claims 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is indefinite and contradictory for a "substantially isolated and purified" cortistatin, which encompasses various degrees of purity, to then require specific dosages

of cortistatin. In other words, a defined dosage depends on the purity of the cortistatin polypeptide itself. Second, the recitation of "at least about 95% amino acid identity" in claim 21 is indefinite and contradictory because the limitation of "about" normally means 95 ± 5%, while the limitation of "at least" removes any lower limit below 95% identity.

It is suggested that amending claims 21 & 23 to remove confusing and redundant language would also more accurately claim the instant invention. For example, "a pharmaceutical composition for.... comprising [from] about 50 *u*g to about 750 *u*g of [a substantially isolated and purified] human cortistatin having at least [about] 95% amino acid [residue] sequence similarity with [a cortistatin having a sequence of] SEQ ID NO:26, [and] which induces cortical slow-wave sleep isoform two.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> The second application (which is called a continuing application) must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the continuing application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *In re Ahlbrecht*, 168 USPQ 293 (CCPA 1971).

Note that because no human cortistatin polypeptides were described in parent application no. 08/648,322, priority is held to be the filing date of parent application 08/857,389 (i.e., 05/15/97).

Claims 21-23 are rejected under 35 U.S.C. 102(a) as being anticipated by Fukusumi et al. (IDS REF #C2).

Fukusumi et al. teach isolation and purification of human cortistatin of SEQ ID NO: 26 (pg. 158, Fig. 1) in pharmaceutical compositions (page 158, 1st col.) that include the pharmaceutically acceptable carrier, AcONH4 buffer (pH 8) and also comprise the pharmaceutically acceptable carrier, H2O, in dosages of between 10 pM and 1μM of cortistatin (Fig.4), as well as dosages of 0.1-1 nmol/ brain (Fig. 7 and page 162), which therefore are between about 50 *u*g to about 750 mg; thereby, meeting the limitations of claims 20, 22 & 24.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (703) 872-9306.

Robert C. Hayes, Ph.D.
August 17, 2004

ROBERT C. HAYES, PH.D.
PATENT EXAMINER